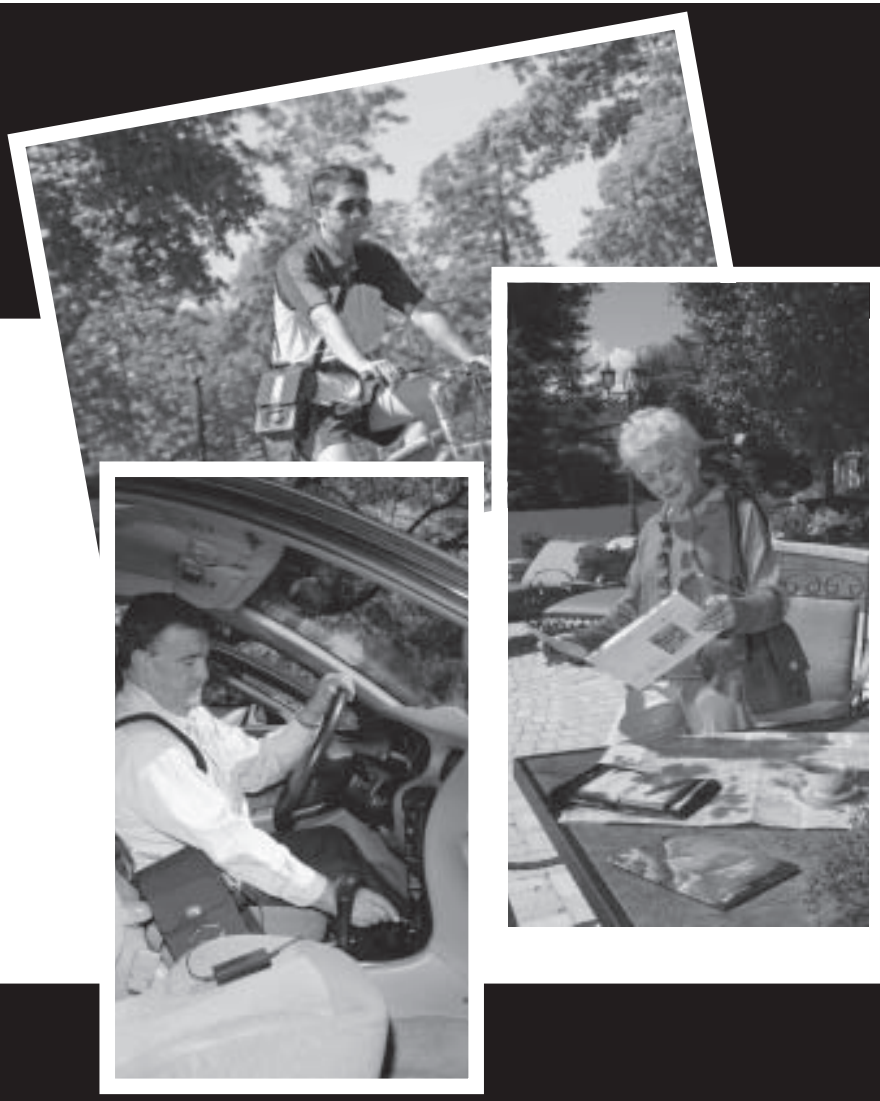
FreeStyle™

Patient Manual

FreeStyle™ Portable Oxygen Concentrator



AirSep®

TABLE OF CONTENTS

AirSep® Freestyle™ Portable Oxygen Concentrator

Why Your Physician Prescribed Oxygen	2
What Is the FreeStyle Portable Oxygen Concentrator?	3
Important Safety Rules	5
Getting Started with your FreeStyle Portable Oxygen Concentrator	8
Battery Charging	10
Nasal Cannula	11
FreeStyle Unit Components	12
Operating Instructions	13
Power Supplies	14
Filter	15
Setting of the Flow Selector for Prescribed Oxygen Concentration	16
Alarm/Light Indicators	17
How to Respond to FreeStyle's Alarm/Light Indicators	19

TABLE OF CONTENTS

AirSep® Freestyle™ Portable Oxygen Concentrator

Cleaning, Care, and Proper Maintenance	**21**
Cabinet	21
Filters	22
Carrying Bag	23
Alarm/Service Indicator	23
FreeStyle Accessories	**24**
Reserve Oxygen Supply	**24**
Troubleshooting	**25**
FreeStyle Specifications	**27**
Classification	28
Symbols	29
Limited Warranty	**30**

AirSep's FreeStyle™ Portable Oxygen Concentrator

This Patient Manual will acquaint you with AirSep's FreeStyle™ Portable Oxygen Concentrator. Make sure you read and understand all the information contained in this manual before you operate your FreeStyle unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

	If you observe that the FreeStyle unit is not working properly, if you feel ill or uncomfortable, or if you are unable to hear and/or feel the oxygen pulse, consult your Equipment Provider and/or your physician immediately.
	This unit is not to be used for life support. Geriatric, pediatric, or any other patient unable to communicate discomfort or hear or see the alarms while using this concentrator may require additional monitoring. A physician should be consulted immediately if the patient is experiencing any signs of patient discomfort.
	This device supplies high-concentration oxygen that promotes rapid burning. Do not allow smoking or open flames within five feet of (1) this device, or (2) any oxygen-carrying accessory. Use no oil, grease, or petroleum-based products on or near FreeStyle. Disconnect the power cord from the electrical outlet before you clean or service the unit.
	While using FreeStyle outdoors with the AC power supply, connect the power supply into a Ground Fault Interrupted (GFI) outlet only. FreeStyle should not be used in the rain without proper protection of the unit.

Why Your Physician Prescribed Oxygen

Many people suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these patients can benefit from supplemental oxygen therapy at home, when traveling, or while participating in daily activities away from home.

Oxygen is a gas that makes up 21% of the room air we breathe. Our bodies depend on a steady supply to function properly. Your physician has prescribed supplemental oxygen therapy because your body is not able to get enough oxygen from room air. Oxygen is a non-addictive drug, and your physician prescribed a flow sufficient to improve your condition.

Please keep in mind that unauthorized oxygen therapy can be dangerous. You must seek medical advice before you use this oxygen concentrator. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate.

	It is very important to select the prescribed level of oxygen flow. Do not increase or decrease the flow until you first consult your physician.
	Use the FreeStyle Portable Oxygen Concentrator during sleep only under the recommendation of a qualified clinician.

What Is the FreeStyle Portable Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970s and have become the most convenient, reliable source of supplemental oxygen available today. Oxygen concentrators are the cost-effective, efficient, and safe alternative to using high-pressure oxygen cylinders or liquid oxygen. An oxygen concentrator provides all the oxygen you need with no cylinder or bottle deliveries required.

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gases. In the FreeStyle unit, room air passes through a regenerative, adsorbent material called "molecular sieve." This material separates the oxygen from the nitrogen. The result is a flow of high concentration oxygen delivered to the patient.

The size and weight of traditional oxygen concentrators have limited their portability. A person who needs oxygen away from home or a hospital has used high-pressure oxygen cylinders and/or liquid oxygen. Oxygen conserving devices (OCDs) have been used to increase the length of time that cylinders last. OCDs deliver oxygen only at the beginning of inhalation, when oxygen is most beneficial. Using this technique, OCDs conserve oxygen.

FreeStyle uses traditional oxygen concentration technology and combines it with oxygen conserving technology. This combination enables a significant reduction in the size of the oxygen concentrator and makes FreeStyle ultra-portable. A typical oxygen concentrator weighs more than 50 pounds. In contrast, your FreeStyle concentrator weighs only 4.4 lbs (2kg).

FreeStyle delivers a flow of oxygen up to an equivalent flow of 3 LPM (liters per minute) in this lightweight package that can be easily carried and used away from home.

FreeStyle operates from four different power sources. (Refer to the Power Supplies section of this manual.)

Important Safety Rules

Carefully review and familiarize yourself with the following important safety information about the portable FreeStyle Oxygen Concentrator.

	In the event of an alarm or if you are experiencing any signs of discomfort, consult your Equipment Provider and/or your physician immediately.
	This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.
	When using FreeStyle in an automobile, boat, or other vehicle with the DC power supply, make sure that the vehicle is started and running before connecting the FreeStyle unit. If the FreeStyle unit is connected to the vehicle while starting it, jumping or charging the vehicle may cause a need to reset the FreeStyle unit's DC power supply. If this occurs, disconnect the DC power supply from the DC outlet, restart your vehicle, and then reconnect your DC power supply into the DC outlet.

	Never use FreeStyle with the device itself located in the trunk of an automobile.
	Do not allow either the air intake filter or the air outlets to become blocked during use.
	When the automobile in which you are using FreeStyle is turned off, disconnect and remove the unit from the automobile with you. Never allow FreeStyle to be stored in a very hot automobile or in other similar, high- or low-temperature environments. (Refer to the Specifications section in this manual.)
	Do not leave a nasal cannula under bed coverings or chair cushions. If FreeStyle is turned on but not in use, the oxygen could make the material flammable. Make sure FreeStyle is off when not in use.
	Although FreeStyle is a low-voltage device, do not remove its housing. Only your Equipment Provider should remove the unit covers.

WARNING	AirSep recommends an alternate source of supplemental oxygen in the event of a power outage, alarm condition, or mechanical failure. Consult your physician or Equipment Provider for the type of reserve system required.
NOTE	Federal (USA) law restricts this device to sale by order of a physician. Use FreeStyle in accordance with AirSep's FreeStyle Patient Manual.

Getting Started with Your FreeStyle Portable Oxygen Concentrator

The FreeStyle packaging contains the following items, as shown in Figures 1-3. If any are missing, contact your Equipment Provider.

- FreeStyle Portable Oxygen Concentrator with carrying case
- Patient manual (not shown)
- AC power supply (100-240 volts, 50/60 Hz) with power cord (alternate power cords available for use in various countries)
- Automobile DC power supply

Figure 1: FreeStyle Unit

Figure 2: FreeStyle AC Power Supply/Power Cord

Figure 3: FreeStyle DC Power Supply

Optionally, you may also have an AirBelt for extended battery life. That packaging contains the following, as shown in Figure 4:

- AirBelt battery belt
- AC power supply (100-240 volts, 50/60 Hz) with power cord (alternate power cords available for use in various countries)

Figure 4: AirBelt and AC Power Supply/Power Cord

Before operating FreeStyle for the first time, familiarize yourself with the locations of the major components. These are illustrated in the figures on the following pages and discussed later in the manual.

Battery Charging

Check to make sure your unit's battery is fully charged before venturing out with FreeStyle for the first time or upon subsequent use. To check the level of charge of the internal battery, press the BATT button on FreeStyle's keypad. The battery gauge/indicator(s) LEDs above the BATT button illuminate to indicate the level of internal battery charge (25-100%).

To charge FreeStyle's internal battery, simply connect its AC power supply or DC power supply into the unit's power connection inlet (as shown in Figure 5) and the other end to its proper AC or DC power outlet. FreeStyle's internal battery will completely recharge from its fully depleted state in approximately 3½ hours. While charging the battery, the battery gauge/indicator(s) on the FreeStyle unit's keypad will illuminate to indicate the level of internal battery charge. When fully charged, all four LEDs will illuminate continously.

The optional AirBelt, which can increase FreeStyle's battery duration to up to 10 hours, requires approximately 3 hours to completely charge when the external battery is fully depleted. To recharge AirBelt, connect its own AC power supply to the end of AirBelt's power cord (as shown in Figure 6), and the other end of the power supply into a proper AC power outlet. A separate battery gauge/indicator for checking the level of charge on the AirBelt's battery is located on this accessory's cord and functions exactly like the internal battery's indicator on the keypad.

Figure 5: Internal Battery Charging

Figure 6: AirBelt Battery Charging

NOTE

If the power supply remains connected when the internal battery is fully charged, the four LEDs will turn off after approximately one hour.

Nasal Cannula

A nasal cannula and tubing are used to deliver oxygen from the FreeStyle unit to the user. The tubing is connected to the unit's oxygen outlet. (See Figure 7.)

Figure 7: Connecting Cannula to FreeStyle's Oxygen Outlet

AirSep recommends a nasal cannula with 7 ft (2.1 m) of tubing, AirSep Part No. CU002-1. Other lengths of tubing up to 25 ft (7.62 m) maximum, including nasal cannula, may be used.

Normally, when the unit is in its carrying case, it will be necessary to first feed the cannula through the specially designed hole in the top center of the case and then to lift the cover of the case to secure the cannula to the oxygen outlet.

FreeStyle Unit Components

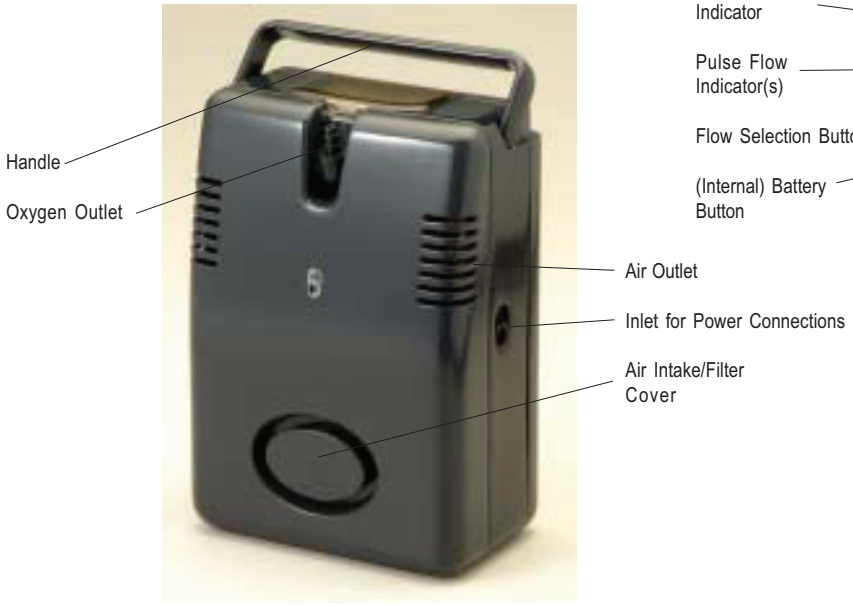


Figure 8: FreeStyle Exterior View - Front

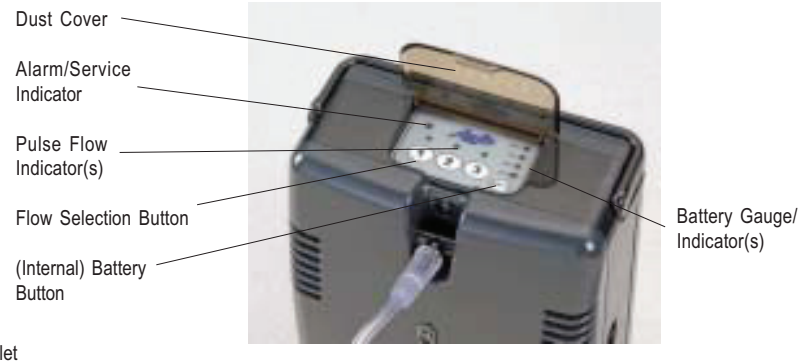


Figure 9: Close-Up of Keypad/Alarm Display

Figure 10: FreeStyle Exterior View - Back

Now that you are familiar with FreeStyle's components, review the instructions on the following page to operate the FreeStyle unit.

Operating Instructions

1. Locate and position FreeStyle so that the air inlets and air outlets are not obstructed. The unit, particularly the air intake area, should be located in a well-ventilated space.
2. Power the unit from (a) the internal battery; (b) AirBelt; (c) DC outlet; or (d) an AC outlet. (Refer to the Power Supplies section of this Patient Manual.)
   a. Use the internal battery only; **or**
   b. Use the AirBelt by connecting it to the FreeStyle unit's inlet.
   c. If you are in an automobile, connect one end of the DC power supply into the FreeStyle unit's inlet and the other end into the DC outlet; **or**
   d. If you are near an AC outlet, connect one end of the AC power supply into the FreeStyle unit's inlet and the other end into the AC outlet.
3. Connect your cannula to the oxygen outlet.
4. Lift the dust cover on the unit.
5. Turn the FreeStyle unit on by pressing the 1, 2, or 3 button on the unit's keypad for the liter flow prescribed by your physician. The green LED above the button selected illuminates. Each time you turn on the FreeStyle unit, a brief alarm sounds. This indicates that FreeStyle is powered for use.
6. To change the pulse flow setting, press the appropriate button. You will observe a change in compressor speed, which is normal.
7. To turn FreeStyle off, press the button corresponding to the pulse flow setting light that is illuminated.

When FreeStyle senses inhalation, oxygen is supplied to you through your cannula. The duration of this pulse flow is dependent upon the flow setting.

The time required to reach maximum oxygen concentration after turning on the FreeStyle unit is approximately two minutes.

Power Supplies

FreeStyle can be powered in four different ways – the internal battery, an AC power supply, DC power supply, and an optional AirBelt battery belt in combination with the unit's internal battery.

1. **Internal Battery:** A rechargeable, internal battery is located within each FreeStyle unit. When it is fully charged, it supplies power to the FreeStyle unit for up to 3 ½ hours. An audible alarm sounds when the battery power is getting low. The alarm is discussed in the Alarm/Light Indicators section of this manual.

   Battery Charging: To charge the internal battery, connect FreeStyle to either the AC power supply and a 100-240 volt, 50/60 Hz AC power outlet, or connect it to a DC power outlet in an automobile (boat, motor home, etc.). It takes a minimum of 3 1/2 hours for a discharged battery to fully charge. It is recommended to recharge the battery, even if only partially depleted, as often as possible.
2. **AC Power Supply:** An AC power supply allows FreeStyle to be connected to a 100-240 volt, 50/60 Hz outlet. The power supply converts 100-240 volt AC to a DC voltage for the FreeStyle unit. When FreeStyle is operated with the AC power supply, power from the AC outlet powers the unit and recharges FreeStyle's battery simultaneously.
3. **DC Power Supply:** A DC power supply can be connected from the FreeStyle unit to an automobile's (boat, motor home, etc.) 12-volt DC outlet. When FreeStyle is connected to the automobile's DC outlet, power from the automobile battery powers the FreeStyle unit and recharges the FreeStyle's battery simultaneously.
4. **Optional AirBelt (External Battery Belt):** FreeStyle can also be powered by an external battery belt. This belt can be worn around the waist, and when used in combination with a fully charged internal battery, supplies power to FreeStyle for up to 10 hours. The belt pack connects to the FreeStyle unit's power inlet, and it can be recharged by connecting it to the battery belt's own power supply.

Filters

Air enters FreeStyle through an air intake filter located under the cover on the lower front of the oxygen concentrator. (See Figures 11 and 12.) This filter prevents dust and other large particles in the air from entering the unit. Before you operate FreeStyle, make sure this filter is clean and positioned correctly.

Figure 11: Removal of Air Intake Filter Cover

Figure 12: Removal of Filter from Filter Cover

NOTE

Use only AirSep Part No. FI144-1 as the air intake filter for this unit.

Setting of the Flow Selector for Prescribed Oxygen Concentration

The FreeStyle unit has three pulse flow settings: 1, 2, and 3, providing flows equivalent to 1–3 LPM oxygen. Lift the dust cover on the unit's keypad, and press the 1, 2, or 3 button, which corresponds to the oxygen pulse flow that your physician has prescribed. (See Figures 13 and 14.)

Figure 13: Lifting Dust Cover on Keypad Display

Figure 14: Pressing Flow Selection Button

CAUTION

It is very important to select only the prescribed level of oxygen flow. Change the pulse flow selection only under the guidance of your physician.

Alarm/Light Indicators

When the FreeStyle unit senses inhalation, a pulse of oxygen is sent through the nasal cannula. The green light above the selected pulse flow setting displays intermittently each time a breath is detected.

Additionally, when the unit is operating on and simultaneously being charged through the AC or DC power supply, the FreeStyle unit's battery gauge/indicator(s) display the charge level of the battery and remain on for approximately one hour after reaching a full charge.

An audible alarm sounds if FreeStyle has a low battery, if the cannula is disconnected, or if performance of the unit is outside specifications. The light and audible alarm conditions are explained in detail below and summarized on the chart later in this section of the manual.

- **Start-Up**

  A brief alarm sounds at start-up. FreeStyle begins to operate when the alarm stops.

- **Low battery**

  As the battery power approaches a low level, a brief alarm sounds intermittently, and the yellow 25% BATT light also illuminates intermittently. When this occurs, connect FreeStyle into a DC power outlet or an AC power outlet, or change to another source of oxygen within two minutes. When FreeStyle is connected to DC power outlet or to an AC power outlet, the unit operates while recharging FreeStyle's battery simultaneously. The level of battery charge is indicated by the battery gauge/indicator(s).

- **Cannula disconnected**

  When FreeStyle is operating but does not sense breathing within a predetermined time period, a constant alarm sounds, and the red alarm/service light illuminates. If this occurs, check the connection from the cannula to the FreeStyle unit, make sure that the nasal cannula is positioned properly on your face, and ensure that you are breathing through your nose. (Your physician may recommend the use of a chin strap if needed.) If the alarm continues to sound, change to an alternate source of oxygen, and contact your Equipment Provider.

- **FreeStyle's capacity is exceeded**

  If your breathing rate causes the capacity of FreeStyle to be exceeded, a rapid alarm sounds, and the red alarm/service light illuminates intermittently. When this occurs, the concentration of oxygen that FreeStyle is supplying is outside of the unit specifications. You should reduce any activity, change to another source of oxygen, and contact your Equipment Provider.

- **General malfunction**

  If FreeStyle has a general malfunction, a rapid alarm sounds, and the red alarm light illuminates continuously. When this occurs, the concentration of oxygen that FreeStyle is supplying is outside of the unit specifications. You should change to another source of oxygen and contact your Equipment Provider.

How to Respond to FreeStyle's Alarm/Light Indicators

Status	Audible Alarm	Light	Indicates	Action
Indicator	Brief, continuous, at start-up	(Green) pulse; continuous light	FreeStyle has been turned on.	You may begin to operate your FreeStyle unit.
Indicator	No	(Green) pulse; intermittent light	FreeStyle is delivering oxygen as a pulse flow.	Continue using FreeStyle normally.
Indicator	No	Level Indicator	Battery charge level.	Charge as indicated.
Indicator	No	(Yellow) continuous light	Service required.	Return unit to Equipment Provider for inspection/service.

Status	Audible Alarm	Light	Indicates	Action
Alarm	Continuous: Beep	(Red) alarm; continuous light	No breath detected by the unit for a predetermined time period.	Check the cannula connection. Ensure that you are breathing through your nose. If the alarm persists, contact your Equipment Provider.
Alarm	Intermittent: Beep, beep, beep...	25% (Yellow) BATT; battery indicator	Battery voltage is too low to operate FreeStyle.	Connect the FreeStyle unit into a DC outlet or an AC outlet immediately.
Alarm	Rapid intermittent: Beep, beep, beep...	(Red) alarm; intermittent light	Breathing rate is exceeding the capacity of the FreeStyle unit.	Reduce activity, and/or locate and use another source of oxygen. Contact your Equipment Provider.
Alarm	Rapid intermittent: Beep, beep, beep...	(Red) alarm; continuous light	General malfunction of the FreeStyle unit has occurred.	Turn off the unit. Change to another source of oxygen, and contact your Equipment Provider.

Cleaning, Care, and Proper Maintenance

Cabinet

	Turn off the FreeStyle unit, and disconnect the power cord from FreeStyle before you clean the cabinet.
	Keep the FreeStyle unit clean and free from moisture and dust. Clean the plastic housing periodically by wiping with a lint-free cloth or with a mild household cleaner applied with a damp cloth or sponge. Pay special attention to the oxygen outlet for the cannula connection to make sure it remains free of dust, water, and particles.
	Do not use liquid directly on the FreeStyle unit to clean it. A list of **undesirable** chemical agents includes, but is not limited to, the following, according to the plastics manufacturer: alcohol and alcohol-based products (isopropyl alcohol), concentrated chlorine-based products (ethylene chloride), and oil-based products (Pine-Sol, Lestoil). These are NOT to be used to clean the plastic housing on FreeStyle. These chemicals and the cleaners that contain them will crystallize the plastic and break down the plastic's molecular properties.
	Replace the disposable cannula periodically following normal usage. Additional supplies are available from your Equipment Provider.
	To prevent a voided AirSep warranty, follow all manufacturer's instructions.

Filter

Air Intake Filter

At least one time each week, remove the cover on the lower front of the unit, and wash the air intake filter, which is positioned on the inside of the cover. Your Equipment Provider may advise you to clean it more often, depending upon your operating conditions. Follow these steps to properly clean the air intake filter:

1. Remove the filter from the air intake filter cover, and wash it in a warm solution of soap and water.
2. Rinse the filter thoroughly, and remove excess water with a soft, adsorbent towel. Ensure that the filter is dry before replacing it.
3. Replace the dry filter.

NOTE	Do not operate FreeStyle without the air intake filter in place. If a second filter is provided, insert the "replacement" filter before you clean the dirty filter.
NOTE	AirSep does not recommend the sterilization of this equipment.

Carrying Bag

To clean the carrying bag and strap, brush only with warm soapy water (Do not saturate the bag.), then allow to air dry. Do not machine wash or dry the bag.

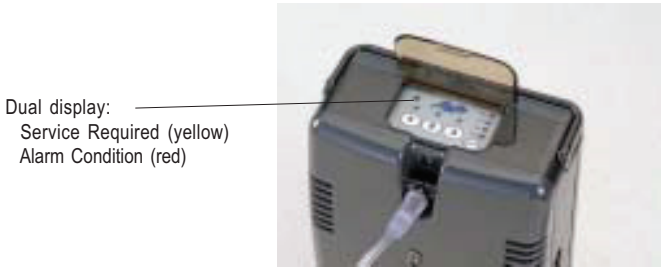


Figure 15: Indicator of Required Inspection/Service

Alarm/Service Indicator

When the alarm service/indicator illuminates (yellow), it is time for your FreeStyle unit to be inspected serviced by your Equipment Provider. After any necessary service and the performance is verified by the Equipment Provider, the alarm service/indicator light will be reset.

FreeStyle Accessories

In addition to the nasal cannula, AirSep recommends that you do not use accessories with FreeStyle other than those listed below as supplied by AirSep through your Equipment Provider. Use of accessories not listed below could adversely affect the performance and/or safety of the FreeStyle Portable Oxygen Concentrator.

Description/Part Number

AC Power Supply with appropriate power cord (PW013-1)
DC Power Supply (PW012-1)
Air Intake Filter (FI144-1)
Carrying Bag (MI235-1, or optionally, MI235-2 black/blue color or MI235-3 beige color)
AirBelt and AirBelt Power Supply with appropriate power cord (BT017-1)

Reserve Oxygen Supply

Your Equipment Provider should provide or suggest an alternative source of supplemental oxygen therapy in case there is a mechanical failure or a power outage. During a power outage, alarm condition, or mechanical failure, use your reserve oxygen supply, and consult your Equipment Provider immediately.

Troubleshooting

The FreeStyle product is designed for years of trouble-free use.

If your FreeStyle Portable Oxygen Concentrator fails to operate properly, refer to the chart on the following pages for possible causes and solutions and, if needed, consult your Equipment Provider.

Do not attempt any maintenance other than the possible solutions listed below.

Problem	Probable Cause	Solution
FreeStyle does not operate when a pulse flow selection button is pressed.	Battery is discharged.	Power the unit through the DC outlet, or an AC outlet.
	Malfunction.	Contact your Equipment Provider, and change to a reserve oxygen supply.
A continuous alarm sounds and the (red) alarm light illuminates continuously.	FreeStyle has not detected a breath for a predetermined time period.	Check the cannula connection.
		Ensure that cannula tubing is not kinked.
		Make sure that the cannula is positioned properly and that you are breathing through your nose.

Problem	Probable Cause	Solution
Intermittent alarm condition, and the (yellow) BATT light illuminates intermittently.	Battery requires charging.	Connect to a DC or an AC outlet within 2 minutes, or connect to the optional AirBelt.
Rapid alarm condition, and the (yellow) BATT light illuminates intermittently, and FreeStyle shuts down.	Battery voltage is too low to operate the FreeStyle unit.	Connect to a DC or an AC outlet immediately, or connect to the optional AirBelt.
Intermittent alarm condition and the (red) alarm light illuminates intermittently.	Breathing rate has exceeded the capacity of the FreeStyle unit.	Change to another source of oxygen, and contact your Equipment Provider.
Intermittent alarm condition, and the (red) alarm illuminates continuously.	A general malfunction has occurred.	Change to another source of oxygen, and contact your Equipment Provider.
Unit does not start on battery power.	Unit may be hot or cold if left outdoors such as in an automobile.	Allow the unit to reach normal operating temperature, which may take several minutes if exposed to temperature extremes. Temporarily connect your AC or DC power supply to the unit's power inlet and power source, as needed, to reset the unit's internal battery.
Unit alarms while in automobile and connected to the DC outlet	No power to the unit if battery depleted and DC outlet not charging	Disconnect the DC power supply from the automobile outlet, restart the automobile, and then reconnect the DC power supply into the automobile DC outlet to reset the circuit
All other problems.		Change to another source of oxygen, and contact your Equipment Provider.

FreeStyle Specifications

Oxygen Concentration:*]	1-3 pulse settings; equivalent to a continuous flow of 90% oxygen
Dimensions:	8.6 in. high x 6.1 in. wide x 3.6 in. deep (21.8 cm high x 15.5 cm wide x 9.1 cm deep)
Weight:	4.4 lb (2.0 kg); 1.8 lb (.8 kg) optional AirBelt
Power:	AC Power Supply: 100 – 240 VAC (1.0 amp at 120 VAC) DC Power Supply 12-16 VDC (6.0 amps at 12 VDC)
Battery duration:	3 LPM – 2 hours; 2 LPM – 2.5 hours; 1 LPM – 3.5 hours Optional AirBelt when combined with the internal battery: 3 LPM – 5 hours; 2 LPM – 6 hours; 1 LPM – 10 hours
Battery recharge time:	3.5 hours; optional AirBelt: 3 hours
Warm-up time:	2 minutes
Battery cycle life:	Approximately 300 cycles, then 80% capacity or below
Audible alarms and pulse visual indicators:	Start-up – audible and visual (GREEN indicator light); Pulse flow – visual (GREEN light); Battery condition – battery level (GREEN indicator lights); cannula disconnect-audible and visual (RED alarm light); System overdraw – audible and visual (RED warning and alarm lights); High and low pressure – audible and visual (RED alarm light); Service required: visual (YELLOW alarm light)
Sound:	Less than 55 decibels
Temperature range:	Operational temperature: 41°F to 104°F (5°C to 40°C) Storage temperature: -2°F to 140°F (-20°C to 60°C)

*Based on an atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C)

Classification

Type of protection against electric shock:

Class II Protection from electric shock is achieved by double insulation.

Degree of protection against electric shock:

Type BF Equipment providing a particular degree of protection against electric shock regarding
1) allowable leakage current;
2) reliability of protective earth connection (if present).
Not intended for direct cardiac application.

Independent testing for Medical Electrical Equipment Standard :

Tested by Intertech Testing Services NA Inc. to be in compliance with EN 60601-1:1988 + A1:1991, A2:1995 General Requirements for safety.

Protection against potential electromagnetic or other interference between the equipment and other devices:

Tested by Ultratech Group of Labs to be in compliance with EN60601-1-2: 2001 Edition (EMC)

Method of cleaning and infection control allowed:

Please refer to the “Cleaning, Care, and Proper Maintenance” section of this FreeStyle Patient Manual.

Degree of safety of application in the presence of flammable anesthetic gases:

Equipment not suitable for such application.

Mode of operation:

Continuous duty.

Symbols

Symbols are frequently used on equipment in preference to words with the intention of decreasing the possibility of misunderstanding caused by language differences. Symbols can also permit easier comprehension of a concept within a restricted space.

The following table is a list of symbols and definitions used with the FreeStyle Portable Oxygen Concentrator.

Symbol	Description
	Warning
	Caution
	Refer to Patient Manual instructions
	Note
	No Oil
	No Smoking
	Type BF equipment

Symbol	Description
	Class II
	CE mark
	Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment.
	Proper disposal of waste of electrical and electronic equipment required.
	Keep unit and accessories dry.
	Do not disassemble

Limited Warranty

AirSep Corporation warrants the FreeStyle Oxygen Concentrator to be free from defect in parts for three years (as specified on the original invoice provided) from the date of delivery to the original purchaser, under normal use and operation. The battery is warrantied for 90 days. AirSep Corporation's obligations under this warranty are limited to the repair or replacement of any such item of equipment (or part thereof) shown to be defective or, at AirSep Corporation's option, to refund the purchase price of any such defective item of equipment.

Each item of equipment for which a warranty claim is asserted shall, at the request of AirSep Corporation, be returned on a prepaid basis with proof of purchase date to the AirSep factory at the expense of the purchaser. The purchaser will be responsible for return freight charges. Replacement parts shall be warranted as stated above for the unexpired portion of the original three-year parts warranty (as specified on the original invoice provided). This warranty does not extend to any item or part subjected to misuse, accident, improper maintenance, or application, or which has been repaired or altered outside of the AirSep Corporation factory without the express prior written authorization of AirSep Corporation.

THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION THE WARRANTY OF MERCHANTABILITY OR THE WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. IT IS EXPRESSLY UNDERSTOOD THAT PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR DEFECT IN PARTS IS LIMITED TO ENFORCEMENT OF AIRSEP CORPORATION'S OBLIGATION AS SET FORTH ABOVE, AND AIRSEP CORPORATION SHALL NOT BE LIABLE TO PURCHASER OR OTHERS FOR LOSS OF USE OF THE EQUIPMENT OR FOR OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

For European representative:

Gavin Ayling
E-mail: eurorepcontact@airsep.com

For service on your FreeStyle Portable Oxygen Concentrator, please contact your local Equipment Provider at:

Manufactured by:
AirSep Corporation
Buffalo, NY 14228-2085 USA